

Sections from Sherman Food, Drug, and Cosmetic Laws Pertaining to HOME MEDICAL DEVICE RETAILER FACILITIES

109948. (a) "Home medical device retail facility" is an area, place, or premises, other than a licensed pharmacy, in and from which prescription devices, home medical devices, or home medical device services are sold, fitted, or dispensed pursuant to prescription. "Home medical device retail facility" includes, but is not limited to, any area or place in which prescription devices, home medical devices, or home medical device services are stored, possessed, prepared, manufactured, or repackaged, and from which the prescription devices, home medical devices, and home medical device services are furnished, sold, or dispensed at retail.

(b) "Home medical device retail facility" shall not include any area in a facility licensed by the department where floor supplies, ward supplies, operating room supplies, or emergency room supplies of prescription devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(c) "Home medical device retail facility" shall not include any area of a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of Division 2 where the supplies specified in subdivision (c) of Section 4057 of the Business and Professions Code are stored or possessed solely for treatment of patients by a licensed home health agency or licensed hospice, as long as all prescription devices are furnished to these patients only upon the prescription or order of health care practitioners authorized to prescribe or order home medical devices or who use home medical devices or who use home medical devices to treat their patients.

109948.1. (a) "Home medical device services" means the delivery, installation, maintenance, replacement of, or instruction in the use of, home medical devices used by a sick or disabled individual to allow the individual to be maintained in a residence.

(b) "Home medical device" means a device intended for use in a home care setting including, but not limited to, all of the following:

- (1) Oxygen delivery systems and prefilled cylinders.
- (2) Ventilators.
- (3) Continuous Positive Airway Pressure devices (CPAP).
- (4) Respiratory disease management devices.
- (5) Hospital beds and commodes.
- (6) Electronic and computer driven wheelchairs and seating systems.
- (7) Apnea monitors.
- (8) Low air loss continuous pressure management devices.
- (9) Transcutaneous Electrical Nerve Stimulator (TENS) units.
- (10) Prescription devices.

(11) Disposable medical supplies including, but not limited to, incontinence supplies as defined in Section 14125.1 of the Welfare and Institutions Code.

(12) In vitro diagnostic tests.

(13) Any other similar device as defined in regulations adopted by the department.

(c) The term "home medical device" does not include any of the following:

(1) Devices used or dispensed in the normal course of treating patients by hospitals and nursing facilities, other than devices delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical devices to an individual's residence.

(2) Prosthetics and orthotics.

(3) Automated external defibrillators (AEDs).

(4) Devices provided through a physician's office incident to a physician's service.

(5) Devices provided by a licensed pharmacist that are used to administer drugs that can be dispensed only by a licensed pharmacist.

(6) Enteral and parenteral devices provided by a licensed pharmacist.

111656. (a) No person shall conduct a home medical device retail facility business in the State of California unless he or she has obtained a license from the department. A license shall be required for each home medical device retail facility owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a home medical device retail facility in more than one location. The license shall be renewed annually and shall not be transferable. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to home medical device retail facilities.

(b) Applications for a home medical device retail facility license shall be made on a form furnished by the department. The department may require any information it deems reasonably necessary to carry out the purposes of this section.

(c) A warehouse owned by a home medical device retail facility the primary purpose of which is storage, not dispensing of home medical devices to patients, shall be licensed at a fee one-half of that for a home medical device retail facility. There shall be no separate or additional license fee for warehouse premises owned by a home medical device retail facility that are physically connected to the retail premises or that share common access.

(d) The department may, at its discretion, issue a temporary license when the ownership of a home medical device retail facility is transferred from one person to another upon any conditions and for the periods of time as the department determines to be in the public interest. A temporary license fee shall be established by the department at an amount not to exceed the annual fee for renewal of a license to conduct a home medical device retail facility.

(e) Notwithstanding any other provision of law, a licensed home medical device retail facility may furnish a prescription device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container

maintained within the facility in accordance with facility regulations of the State Department of Health Services set forth in Title 22 of the California Code of Regulations.

(f) The licensure requirements of this section shall not apply to the following entities or practitioners, unless the entities or practitioners furnish home medical devices or home medical device services through a separate entity including, but not limited to, a corporate entity, division, or other business entity:

(1) Home health agencies that do not have a Part B Medicare supplier number.

(2) Hospitals, excluding providers of home medical devices that are owned or related to a hospital.

(1) Manufacturers and wholesale distributors, if not selling directly to the patient.

(4) Health care practitioners authorized to prescribe or order home medical devices or who use home medical devices or who use home medical devices to treat their patients.

(5) Licensed pharmacists and pharmacies. Pharmacies that sell or rent home medical devices shall be governed by the provisions of Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code and any rules and regulations adopted by the California State Board of Pharmacy.

(1) Licensed hospice programs.

(2) Licensed nursing homes.

(3) Licensed veterinarians.

(4) Licensed dentists.

(10) Emergency medical services provider.

(11) Breast feeding support programs.

111656.1. (a) After January 1, 2002, prior to issuing a license required by Section 111656, the department shall inspect each place of business to determine ownership, adequacy of facilities, and personnel qualifications. The department shall inspect each licensee at least annually thereafter. Nothing in this section shall prohibit the department from inspecting any medical device retail facility prior to January 1, 2002.

(b) The annual license fee for a home medical device retail facility shall be eight hundred fifty dollars (\$850) until adjusted pursuant to subdivision (c).

(c) The annual license fee required by Sections 111656 and 111630 shall be adjusted annually, commencing July 1, 2003, by the department so that license fee revenues cover the estimated licensing program costs. Adjusted fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.

(d) Commencing July 1, 2003, the department shall by July 30 of each year, publish the amount of fees to be charged as adjusted pursuant to this section. This adjustment of fees shall not be subject to the requirements of

Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(e) Commencing January 1, 2003, the department shall, on or before January 10 of each year, provide the Legislature with a report recommending fee rates. The report shall describe the estimated licensing program costs for the next fiscal year to carry out the licensing, regulating, inspecting, and other duties and responsibilities of the department in carrying out the provisions of this article. The department shall describe the projected license fee amount so that license fee revenues cover the estimated licensing program costs. Projected fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.

(f) The Drug and Device Safety Fund is hereby created as a special fund in the State Treasury. All moneys collected by the department under this section and Sections 111656.7, 111656.8, 111656.12, and 111630, and fines and penalties collected by the department in the enforcement of this article, shall be deposited in the fund for use by the department upon appropriation by the Legislature for the purposes of providing funds necessary to carry out and implement the provisions of this article relating to drugs and devices.

111656.2. (a) The following standards shall apply to all home medical device retail facilities:

(1) Each retail facility shall store prescription devices in a manner that does not allow a customer direct access or self-service.

(2) Each retail facility shall maintain the premises, fixtures, and equipment in a clean and orderly condition.

(3) Each retail facility shall maintain the premises in a dry, well-ventilated condition, free from contamination or other conditions that may render home medical devices unfit for their intended use.

(b) The department may by regulation impose any other standards pertaining to the acquisition, storage, and maintenance of prescription devices or other goods or to the maintenance or condition of the licensed premises of any home medical device retail facility as the department determines are reasonably necessary.

111656.3. (a) Each home medical device retail facility shall have written policies and procedures related to home medical device handling and, if authorized by the department pursuant to Section 111656.4, the dispensing of prescription devices. Those written policies and procedures shall be adequate to assure compliance with this article and shall include, but not be limited to:

(1) Training of staff, patients, and caregivers.

(2) Cleaning, storage, and maintenance of home medical devices necessary to prevent damage or contamination and to assure their operation in accordance with manufacturer specifications.

(3) Emergency services. If home medical device malfunction may threaten a patient's health, access to emergency services 24 hours per day, 365 days per year shall be available for device maintenance or replacement.

(4) Maintaining all records required by this article and any regulations adopted pursuant to the provisions of this article.

(5) Storage and security requirements to assure that prescription devices are dispensed in accordance with this article.

(6) Quality assurance.

(b) The home medical device retail facility shall make consultation available to the patient or primary caregiver about the proper use of devices and related supplies furnished by the home medical device retail facility. The home medical device retail facility shall notify the patient or primary care giver that this consultation is available.

(c) Each home medical device retail facility shall ensure all personnel who engage in the taking of orders for, the selling of, or the fitting of prescription devices, if authorized by the department pursuant to Section 111656.4, shall have training and demonstrate initial and continuing competence in the order-taking, fitting, and sale of prescription devices that the home medical device retail facility furnishes pursuant to Section 111656.4.

(d) Each home medical device retail facility shall prepare and maintain records of training and demonstrated employee competence required under this article for employees of the home medical device retail facility. The records shall be maintained for three years from and after the last date of employment.

(e) Each home medical device retail facility shall have an ongoing, documented quality assurance program that includes, but is not limited to, the following:

(1) Monitoring personnel performance to assure compliance with this article.

(2) Storage, maintenance, and dispensing of prescription devices to assure that prescription devices are dispensed in accordance with this article.

(f) The records and documents specified in subdivisions (a) and (e) shall be maintained for three years from the date of making. The records and documents described in subdivisions (a), (d), and (e), shall be open to inspection at all times during business hours by authorized agents of the department or an inspector from the California State Board of Pharmacy for the purpose of investigating a pharmacist.

111656.4. Section 4051 of the Business and Professions Code shall not prohibit a home medical device retail facility from selling or dispensing prescription devices if the department finds that sufficient qualified supervision is employed by the home medical device retail facility to adequately safeguard and protect the public health. Each person applying to the department for this exemption shall meet the following requirements to obtain and maintain the exemption:

(a) A licensed pharmacist or an exemptee who meets the requirements set forth in paragraphs (1) to (5), inclusive, and whose license of exemption is currently valid, shall be in charge of the home medical device retail facility.

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices.

(3) He or she shall complete a training program that addresses each of the following subjects that are applicable to him or her:

(A) Knowledge and understanding of state and federal laws relating the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of state and federal laws relating the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding relating to the safe storage and handling of home medical devices.

(F) Knowledge and understanding of prescription terminology, abbreviations, and format.

(4) The department may, by regulation, require training programs that include additional material.

(5) The department shall not issue an exemptee license until the applicant provides proof of completion of the required training that the department determines is adequate to fulfill these requirements.

(b) The licensed pharmacist or exemptee shall be on the premises at all times that prescription devices are available for sale or fitting unless the prescription devices are stored separately from other merchandise and are under the exclusive control of the licensed pharmacist or exemptee. A licensed pharmacist or an exemptee need not be present in the warehouse facility of a home medical device retail facility unless the department establishes that requirement by regulation based upon the need to protect the public.

(c) The department may require an exemptee to complete a designated number of hours of coursework in department-approved courses of home health education in the disposition of any disciplinary action taken against the exemptee.

(d) Each premises maintained by a home medical device retail facility shall have a license issued by the department and shall have a licensed pharmacist or exemptee on the premises if prescription devices are furnished, sold, or dispensed.

(e) A home medical device retail facility may establish locked storage (a lock box or locked area) for emergency or after working hours furnishing of prescription devices. Locked storage may be installed or placed in a service vehicle of the home medical device retail facility for emergency or after hours service to patients having prescriptions for prescription devices.

(f) The department may by regulation authorize a licensed pharmacist or exemptee to direct an employee of the home medical device retail facility who operates the service vehicle equipped with locked storage described in

subdivision (e) to deliver a prescription device from the locked storage to patients having prescriptions for prescription devices. These regulations shall establish inventory requirements for the locked storage by a licensed pharmacist or exemptee to take place shortly after a prescription device has been delivered from the locked storage to a patient.

111656.5. (a) No person other than a licensed pharmacist, an intern pharmacist, an exemptee, as specified in Section 111656.4, or an authorized agent of the department or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the license issued by the department wherein prescription devices are stored, possessed, prepared, manufactured, or repacked, except that a licensed pharmacist or exemptee shall be responsible for any individual who enters the medical device retail facility for the purposes of receiving, fitting, or consultation from the licensed pharmacist or exemptee or any person performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the home medical device retail facility. The licensed pharmacist or exemptee shall remain present in the home medical device retail facility any time an individual is present who is seeking a fitting or consultation. However, a licensed pharmacist or an exemptee need not be present on the premises of a home medical device retail facility at all times of its operation and need not be present in a warehouse facility owned by a home medical device retail facility unless the department establishes that requirement by regulation based upon the need to protect the public. The exemptee need not be present if the prescription devices are stored in a secure locked area under the exclusive control of the exemptee and unavailable for dispensing. This subdivision shall apply only to prescription devices.

(b) A "warehouse" as used in this section, is a facility owned by a home medical device retail facility that is used for storage only. There shall be no fitting, display, or sales at that location. A licensed pharmacist or exemptee shall be designated as "in charge" of a warehouse but need not be present during its operation. The licensed pharmacist or exemptee may permit others to possess a key to the warehouse.

(c) Notwithstanding the remainder of this section, a home medical device retail facility may establish a locked facility, meeting the requirements of Section 111656.4, for furnishing prescription devices to patients having prescriptions for prescription devices in emergencies or after working hours.

(d) The department may establish reasonable security measures consistent with this section as a condition of licensing in order to prevent unauthorized persons from gaining access to the area, place, or premises, or to the prescription devices therein.

(e) The department may by regulation establish labeling requirements for prescription devices sold, fitted, or dispensed by a home medical device retail facility as it deems necessary for the protection of the public.

111656.6. Home medical devices for rental purposes shall at all times while under the control of the home medical device retail facility, be maintained in a

clean and sanitary condition and in good working order following, where available, manufacturer specifications.

111656.7. (a) Without registering as an out-of-state home medical device retail facility, an out-of-state home medical device retail facility shall not sell or distribute prescription devices in this state through any person or media other than a wholesaler who is licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code.

(b) Applications for an out-of-state home medical device retail facility registration shall be made on a form furnished by the department. The department may require any information it deems reasonably necessary to carry out the purposes of this section.

(c) The Legislature by enacting this section does not intend a registration issued to any out-of-state home medical device retail facility pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state home medical device retail facility.

(d) The Legislature by enacting this section does not intend a registration issued to any out-of-state home medical device retail facility pursuant to this section to serve as any evidence that the out-of-state home medical device retail facility is doing business within this state.

111656.8. (a) No person acting as principal or agent for any out-of-state home medical device retail facility who has not obtained a registration from the department pursuant to this article and who sells or distributes prescription devices in this state that are not obtained through a wholesaler who has obtained a license pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, shall conduct the business of selling or distributing prescription devices within this state without registering with the department pursuant to this article.

(b) Registration of persons under this section shall be made on a form furnished by the department. The department may require any information as the department deems reasonably necessary to carry out the purposes of this section including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose prescription devices he or she is selling or distributing.

(c) The department may deny, revoke, or suspend the registration of persons registered under this article for any violation of this article or Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code or for any violation of Part 5 (commencing with Section 109875) of Division 104. The department may deny, revoke, or suspend the person's registration if the manufacturer whose prescription devices he or she is selling or distributing violates this article or Chapter 9 (commencing with Section 4000) of Division 2 of

the Business and Professions Code or Part 5 (commencing with Section 109875) of Division 104.

(d) Registration under this section shall be renewed annually.

111656.9. When, in the opinion of the department, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a home medical device retail facility that does not meet all of the requirements for licensure as a home medical device retail facility, the department may waive any licensing requirements for that medical device retail facility.

111656.10. (a) The department may void the license of a home medical device retail facility, if the licensed premises remain closed, as defined in subdivision (e), other than by order of the department. For good cause shown, the department may void a license after a shorter period of closure. To void a license pursuant to this subdivision, the department shall make a diligent, good faith effort to give notice by personal service on the licensee. If no written objection is received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the department may void the license without the necessity of a hearing. If the licensee files a written objection, the department shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the department shall have all the powers granted in that chapter.

(b) In the event that the license of a home medical device retail facility is voided pursuant to subdivision (a) or revoked or a home medical device retail facility notifies the department of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all prescription devices to another licensee authorized to possess the prescription devices. The licensee transferring the prescription devices shall immediately confirm in writing to the department that the transfer has taken place.

(c) If a home medical device retail facility fails to comply with subdivision (b), the department may seek and obtain an order from the superior court in the county in which the home medical device retail facility is located, authorizing the department to enter the home medical device retail facility and inventory and store, transfer, sell, or arrange for the sale of, prescription devices found in the home medical device retail facility.

(d) In the event that the department sells or arranges for the sale of any prescription devices pursuant to subdivision (c), the department may retain from the proceeds of the sale an amount equal to the cost to the department of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the prescription devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the prescription devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) Where a statute or regulation requires the licensee to file with the department his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the department, and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the department for the remaining proceeds within 30 calendar days after the personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the department into the Drug and Device Safety Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a home medical device retail facility to be open seven days a week.

111656.11. (a) It is unlawful for any person who is neither a licensed pharmacist nor an exemptee to take charge of a home medical device retail facility or to furnish prescription devices except as otherwise provided in this article.

(b) It is unlawful for any person who has obtained a license to conduct a home medical device retail facility to fail to place a licensed pharmacist or exemptee in charge of that home medical device retail facility or for any person to, by himself or herself, or by any other person, permit the compounding or dispensing of prescriptions, except by a licensed pharmacist or exemptee or as otherwise provided in this article.

111656.12. (a) The fee for examination and investigation for an exemptee license under Section 111656.4 shall be one hundred dollars (\$100).

(b) The fee for an exemptee license and annual renewal under Section 111656.4 shall be one hundred fifty dollars (\$150).

(c) The fee for registration as an out-of-state home medical device retail facility or as the principal or agent of an out-of-state home medical device retail facility shall be one hundred fifty dollars (\$150).

111656.13. (a) Any entity that prior to July 1, 2001, holds a current, valid license as a medical device retailer pursuant to Section 4130 of the Business and Professions Code, shall be deemed to be a licensed home medical device retail facility until the expiration of that license if the entity is in compliance with all applicable criteria for obtaining a license as a home medical device retail facility.

(b) Any entity that was not required to obtain a license as a medical device retailer in order to provide equipment or services prior to July 1, 2001, and that is required to obtain a license as a home medical device retail facility pursuant to

Section 111656, shall apply for a license as a home medical device retail facility by July 1, 2001; however, the requirement for licensure shall only apply to those entities on and after January 1, 2002.